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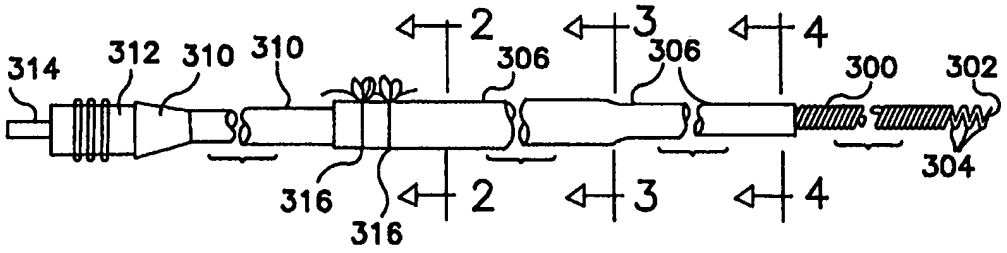

(57) Abstract

A cardioversion or defibrillation system including a cardioverter or defibrillator and a lead. The lead carries a single cardioversion/defibrillation electrode formed of one small diameter metal filament for location in a heart chamber and may include a pace/sense electrode. The small diameter defibrillation electrode extends distally from the distal end of the lead body and may have the length of its extension adjusted by means of a movable sheath.

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INTRACARDIAC DEFIBRILLATION SYSTEM

FIELD OF THE INVENTION

The present invention relates to medical stimulators and leads generally, and more particularly to implantable bradyarrhythmia and tachyarrhythmia leads, particularly intracardiac cardioversion/defibrillation leads having one or more small diameter elongated defibrillation electrodes.

BACKGROUND OF THE INVENTION

In the design of implantable defibrillation electrodes, it has traditionally been understood to be desirable to achieve a low impedance to the delivered current of the defibrillation pulse by employing low resistance materials, providing as large an electrode area as is practical for the implant site, and distributing that surface area over an even larger area. Early attempts to employ large diameter, endocardial leads bearing elongated, surface mounted, right ventricular electrodes showed that the necessary low impedance to allow use with implantable defibrillators was not possible to obtain. As a result, early automatic implantable cardioverter/defibrillators used large surface area, epicardial defibrillation patch electrodes that conformed to surface areas of the heart. However, the stress, pain and expense of the required thoracotomy to position the electrodes gave incentive to the development of the wide variety of endocardial defibrillation leads.

More recently, improvements in electrode materials and lead construction, the delivered shock waveforms and electrode combinations for optimal cardioversion pathways have allowed the clinical use of intracardiac electrodes in the right ventricle and/or right atrium. Currently available implantable ventricular defibrillators typically employ epicardial or subcutaneous patch electrodes, alone, or in conjunction with one or more endocardial leads with one or more electrodes disposed within a heart chamber or blood vessel. Other contemplated multi-lead and multi-electrode atrial and/or ventricular defibrillation systems are widely disclosed, as exemplified in U.S. Patent Nos. 4,708,145 to Tacker, et al., 4,998,975 to Cohen et al., 5,007,436 to Smits, 5,099,838 to Bardy, 5,107,834 to Ideker et al, 5,111,811 to Smits, 5,165,403 to Mehra, and 5,174,288 to Bardy et al.

Ventricular defibrillation is typically effected with at least one electrode disposed within the right ventricle extending along the length of the endocardial lead body and one or more electrodes disposed outside the right ventricle. Many versions of right ventricular defibrillation electrodes have been disclosed in the above listed patents and in further single endocardial lead systems as shown, for example, in further U.S. Patent Nos. 4,481,953 to Gold et al., 4,161,952 to Kinney, et al., 4,934,049 to Kiekhafer et al., 5,010,894 to Edhag, 5,042,143 to Holleman, et al., 5,050,601 to Kupersmith et al., 5,133,365 to Heil, Jr. et al., and 5,144,960 to Mehra et al. Conventionally, it is considered desirable that the surface areas of the electrodes be as large as possible to reduce electrode impedance and thereby reduce defibrillation thresholds. The electrode leads described in the above-cited patents, while providing adequate performance, do tend to be fairly large leads, often in the range of 8 - 10 French in diameter. While the large diameters of these leads do allow for increased electrode surface areas, particularly in the context of lead systems in which multiple leads must be passed down the same vein to access the heart, the sizes of these leads can be problematic.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a cardioversion/defibrillation lead for intra-atrial or intra-ventricular implantation that provides for a wide distribution or dispersion of cardioversion/defibrillation energy. Typically in the past this result has been accomplished by means of electrodes having surface areas as large as possible consistent with location within the chamber to be defibrillated. However, the present invention pursues this goal using a lead carrying only one small diameter elongated defibrillation electrode. The inventors have surprisingly learned that it is possible to rely on the conductivity of the blood within the heart chamber to be defibrillated to accomplish dispersion of the cardioversion/defibrillation energy from a single, small diameter defibrillation electrode, without the increase in defibrillation threshold that would be expected from the reduction in electrode diameter. In the present invention, the lead body takes the form of a single, non-diverging filament, with the electrode located along or extending distally from the lead body, along the

axis of the lead body and the defibrillation electrode takes the form of a wire filament employed as the sole defibrillation electrode within a chamber of the heart.

A single, small diameter wire filament may be the only electrode on the lead, requiring the use of an additional lead carrying one or more pace/sense electrodes if they are desired for use in the chamber in which the defibrillation electrode is implanted. In an alternative embodiment of the invention, a slightly larger diameter defibrillation electrode is provided, which, while still substantially reduced in diameter as compared to comparable prior leads, has sufficient cross sectional area to allow inclusion of a second conductor so that a pace/sense electrode may be included on the lead. The lead may optionally be provided with a sliding, insulative sheath, allowing adjustment of the exposed length of the defibrillation electrode. The configuration of leads according to the present invention may be optimized to produce a small over-all diameter by fabricating the exposed defibrillation electrode as part of the same wire or cable which couples the defibrillation electrode to an implantable cardioverter/defibrillator, avoiding the increase in lead diameter often necessitated by mechanical interconnection of electrodes and conductors.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects, advantages and features of the present invention will be more readily understood from the following detailed description of the preferred embodiments thereof, when considered in conjunction with the drawings, in which like reference numerals indicate identical structures throughout the several views, and wherein:

Figure 1 is a plan view of a first embodiment of a lead according to the present invention.

Figures 2, 3 and 4 are cross-sections through the lead illustrated in Figure 1.

Figure 5 is a plan view of a variant of the lead illustrated in Figure 1.

Figures 6, 7 and 8 are cross-sections through the lead illustrated in Figure 5.

Figure 9 illustrates the method of use of the leads illustrated in Figures 1 and 5.

Figure 10 illustrates an additional alternative embodiment of a lead according to the present invention.

Figure 11 is a side, cutaway view of a portion of the distal end of the lead illustrated in Figure 10.

Figure 12 illustrates a method of use of the lead illustrated in Figure 10.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is realized in a number of preferred embodiments and variations thereof as described in detail hereafter. It will be understood that specific features of the invention that may be implemented in any of the embodiments and variations thereof are depicted in one or more of the figures and/or described herein.

Figure 1 illustrates a side, plan view of a first embodiment of a defibrillation lead according to the present invention, having a single defibrillation electrode taking the form of an exposed length of a small diameter coil 300. The lead body is takes the form of a single, non-diverging filament formed of two overlapping insulative sheaths including a proximal sheath 310 and a slidable distal sheath 306. Coil 300 extends from the distal end of sheath 306, along the central axis of the lead body. Coil 300 may, for example, take the form of a mono-filar or multi-filar close wound coil of wire having a diameter on the order of .004 inches, wound into a coil having a diameter preferably less than or equal to about two French, (i.e. about .030 inches in diameter or less), more preferably less than or equal to about one French (i.e., about .015 inches in diameter or less).

In the embodiment illustrated, the coil 300 takes the form of a mono-filar coil in which the distal tip 302 is sharpened and the distal turns 304 are pulled apart somewhat to provide for a fixation helix, which may be screwed into heart tissue. The exposed length of the coil 300 may be adjusted by movement of the outer insulative sheath 306, which may be moved proximally or distally over the electrode 300 to expose differing lengths of electrode coil. Preferably, sheath 306 is adjustable to allow for electrode coil 300 to have an exposed length of between 2 and 5 inches, to allow for adjustments of a lead to fit hearts of differing sizes. The outer sheath 306 is provided with a step up in diameter at 308, in order to allow it to surround a second insulative sheath 310 which terminates distally at a point proximal to shoulder 308 and extends proximally until connector assembly 312. Conductor 300 extends

proximally within the lead body formed of sheaths 306 and 310 to the connector assembly 312, wherein it is connected to coupled to connector pin 314.

The location of insulative sheath 306, after adjustment, is fixed relative to the electrode coil 300 and insulative sheath 310 by means of one or more sutures 316, or alternatively, may be fixed in place by means of a compressive clamp or other mechanical mechanism. The point at which shoulder 308 comes in contact with the distal end of sheath 310 defines the most proximal position for sheath 306, while a point at which the overlap of the proximal end of sheath 306 with sheath 310 defines the distal-most location of sheath 306. The locations at which the cross-sections illustrated in Figures 19, 20, and 21, are also illustrated on Figure 18 and are discussed below.

Figure 2 illustrates a cross-section through the lead in a proximal portion of a lead, where slidable sheath 306 overlaps sheath 310. Coil 300 is illustrated as located within sheath 310 at this point.

Figure 3 illustrates a cross-section through the lead at a point just proximal to the shoulder 308. Sheath 306 is illustrated in cross-section. The distal end surface of sheath 310 is illustrated, as well as coil 300.

Figure 4 illustrates a cross-section of the lead at a point distal to the shoulder 308 of sheath 306. Surface of the shoulder 308 is visible, as is the cross-section through sheath 306, surrounding coil 300.

It should be noted that in the invention as illustrated, it is anticipated that body fluid may infiltrate into the lead body, entering through the proximal end of sheath 306. This is not believed to be a significant problem. However, in an alternate embodiment of the invention (not illustrated), it may also be desirable to provide a silicone rubber core through the center of conductor 300, to assist in minimizing both fluid infiltration and tissue ingrowth into coil 300.

Figures 5 - 8 illustrate a variant of the lead illustrated in Figures 1 - 4. In this embodiment of the invention, the connector assembly 412, connector pin 414, proximal insulative sheath 410 and distal insulative sheath 406 and sutures 416 correspond to connector assembly 312, connector pin 314, proximal sheath 310, distal sheath 306 and sutures 316 illustrated in Figure 1. In the variant illustrated in Figures

5 - 8, a single cable 400, is substituted for the coiled conductor 300 in the lead illustrated in Figure 18. A sharpened fixation helix 404 is located at its distal end, coupled to cable 400 by means of a crimp sleeve 402. Cable 400 may take the form of a seven wire strand cable or an enlarged cable of seven cables of seven strands each, having an outer diameter of no greater than about two French, preferably one French or less. Movement of distal sheath 406 relative to cable 400 provides an electrode preferably having a length between about two and about five inches (about five to about thirteen cm.) in precisely the manner described above in conjunction with Figure 18. The locations of the cross-sections through the lead illustrated in Figures 6, 7, and 8, are also shown in Figure 5.

Figure 6 illustrates a cross-section through the lead of Figure 5 at a point proximal to the shoulder 408, at a point in which the distal sleeve 406 overlaps the proximal sheath 410. Cable 400 is visible in cross section..

Figure 7 illustrates a cross-section through the lead illustrated in Figure 5 at a point just proximal to the shoulder 408, with sheath 406 visible in cross-section and the end surface of proximal sheath 410 visible surrounding the cable 400.

Figure 8 shows a cross-section through a body of the lead illustrated in Figure 5 at a point distal to the shoulder 408 of distal sheath 406. The shoulder 408 is visible, as is a cross-section through the distal sheath, surrounding cable 400.

Figure 9 illustrates the mechanism by which the leads illustrated in Figures 1 and 5 may be employed in conjunction with the stimulation of a human heart. While the specific lead illustrated is that shown in Figure 5, it should be understood that the same basic mechanism applies to the lead illustrated in Figure 1. The lead is first advanced by means of an introducer or guide catheter as described above in conjunction with the lead of Figure 1 to a point where the fixation helix 404 can be screwed into the ventricle, at a desired location, which may be the apex or other location within the ventricle. Distal sheath 406 may then be adjusted relative to proximal sheath 410, while defibrillation thresholds are taken, to determine the ideal exposed length of cable 400. Upon determination of the ideal exposed length, sutures 416 are employed to stabilize the distal sheath 406 relative to the proximal sheath 410, and the connector assembly 412 is coupled to an implantable defibrillator or

cardioverter 420. In conjunction with the lead illustrated in Figure 5, the implanted defibrillator/cardioverter employs a second lead for pacing and sensing in the ventricle, comprising an elongated insulative lead body 422, carrying a ring electrode 424 and a helical, tip electrode 426 which may be screwed into the right ventricle. Alternative forms of pacing/sensing leads of types known to the art may, of course, be substituted.

Figure 9 illustrates a side, plan view of an additional embodiment of a lead according to present invention. This lead is provided with a connector assembly 500 at its proximal end provided with a connector ring 502 and a connector pin 504. Sealing rings 506 and 508 are provided to seal the lead within the connector block of the associated implantable defibrillator, in a conventional fashion. An elongated, non-diverging lead body 510 extends distally from the connector assembly 500 and takes the form of a bi-lumen tube of polyurethane, silicone, or other similar biocompatible plastic. A defibrillation coil electrode 512 is visible located along the distal portion of the lead, and a helical electrode 514 is shown located at the distal most extremity of the lead. Electrode 514 is coupled to connector pin 504 by means of a coiled or cabled conductor located within a first lumen extending longitudinally within lead body 510. Coil electrode 512 is a continuation of a coiled conductor located in a second lumen within the lead body 510, extending proximally to and coupled to connector ring 502. Overall, it is desirable that the lead have a diameter in the vicinity of electrode 512 of 4 French or less, which may be accomplished in the context of a bipolar lead, by employing the structure and method of manufacture illustrated in Figure 9.

Figure 10 illustrates a side, cutaway view through the lead of Figure 9, in the region of electrode coil 512. In this view, it can be seen that a lead body 510 is provided with two internal lumens 516 and 518, which extend side by side along the length of lead body 510. A first multi-filar coiled conductor 520 is shown in the first lumen 518, conductor 520 extends distally to fixation helix 514 and extends proximally to connector pin 504. A cabled conductor or mono-filar coil conductor may also be substituted for conductor 520. In this view it can be seen that coil electrode 512 takes the form of an elongated multi-filar coil having a relatively short,

distally extending portion 512a wound at a smaller diameter and a relatively longer, proximal extending portion 512b, also wound at a smaller diameter than exhibited by the electrode coil 512 along the portion of the lead over which electrode 512 is exposed.

Rather than employing sleeves, crimps, swages or other relatively complicated interconnected mechanisms, the lead according to the present invention is fabricated according to a methodology produces a structure which allows for a substantial reduction in the overall cross-section size of the lead. Electrode coil 512 is fabricated as an expanded diameter portion of an elongated multi-filar coil, which has a length appropriate to extend from the expanded diameter portion which will serve as the coil electrode, all the way proximally to the connector assembly. This elongated, reduced diameter portion of the coil is inserted into the first lumen 516 through an aperture such as a slot or slit 522, cut in the outer wall of the lumen. The coil is then slid proximally until the increased diameter portion of the coil 512 reaches the slit or slot 522. The expanded diameter portion of the coil may either then be wound around the lead body 510. The expanded diameter portion of electrode coil 512 is then compressed longitudinally, to form a close wound coil so that the distal end of the relatively shorter reduced diameter portion of the coil 512a may be inserted into a second slot 524. Upon re-expansion of the coil, the reduced diameter portion 512a moves distally, securing the distal end of the coil 512 relative to the lead body 510. The portion of the lead lumen 516 adjacent the slots 522 and 524 may then be back filled with adhesive 526, both to seal the lumen 516 against ingressive fluids and to provide a strain relief at the ends of the exposed portions of the electrode coil 512. For sake of simplicity, the back fill 526 is illustrated in the vicinity of slot 522 but should be understood to also be present in the vicinity of slot 524.

An alternative construction technique may be to slide the reduced diameter portion 512b of the coil 512 proximally until the expanded diameter portion of the coil reaches the distal end of the lead body 510, thereafter inserting the distal end of the lead body into the expanded diameter portion of the coil 512, and thereafter moving the coil proximally along the lead body until the expanded diameter portion of

the coil reaches the slot 522, with the rest of the assembly procedure as described above.

By means of this simplified structure and assembly mechanism, it is not necessary to provide for the additional cross-sectional area generally required by prior art interconnection mechanisms for connecting a conductor to an exposed defibrillation electrode coil on a defibrillation lead. One particular proposed embodiment of the lead as illustrated employs an elongated lead body 510 fabricated of a bi-lumen polyurethane tube fabricated of a polyurethane having a relatively high durometer, such as 55D or higher durometer polyurethane, and employs a quadri-filar defibrillation coil electrode 512 manufactured of silver cored MP35N or tantalum wire, coated with platinum, having an overall outer diameter in the expanded diameter portion of the coil approximately 4 French or less . Preferably, the exposed, expanded portion of the coil 512 has a length in the vicinity of two inches (at least about 5 cm.), however other lengths may also be employed. Although not illustrated, a slidable sheath as used in the leads of Figures 1 and 5 may optionally be employed to adjust the exposed length of the coil electrode.

Figure 11 illustrates a lead as illustrated in Figure 9, as implanted in the human heart. Implantation of the lead may be accomplished using the same procedure as described above in conjunction with the implantation of the leads described in Figures 1 and 5, by advancing the lead down an introducer or guide catheter, screwing helical electrode 514 into the tissue of the ventricle, removing the guide catheter or extended introducer, and connecting the connector assembly 500 to an implantable defibrillator 530. All other labeled elements correspond to identically numbered elements illustrated in Figure 9.

The small diameter defibrillation leads illustrated in Figures 1, 5, and 9 are all shown as provided with helical fixation members, typically taking the form of electrodes, as a mechanism for anchoring the tips of the leads in the heart. It should be understood that the embodiments of the inventions illustrated in these figures may also alternatively be practiced in conjunction with the use of one or more pliant tines, or other fixation mechanisms located at the distal ends of the lead bodies.

CLAIMS

1. An implantable electrical cardioversion system, comprising:

a lead having an elongated lead body having proximal and distal ends and an internal longitudinal lumen, a defibrillation electrode means for delivering cardioversion or defibrillation energy to a chamber of a patient's heart consisting of a single conductive filament extending from the lead body and having a length exterior to the lead body of at least about two inches (at least about five cm.) and having an outer diameter no greater than about two French and an electrical coupler, electrically coupled to the conductive filament; and

an implantable cardioverter or defibrillator coupled to the electrical coupler.

2. A system according to claim 1 wherein the conductive filament has an outer diameter no greater than about one French.

3. A lead according to claim 1 or claim 2 wherein the conductive filament is a stranded metal conductor.

4. A lead according to claim 1 wherein the conductive filament is a metal coil having an outer diameter no greater than about two French.

5. A lead according to claim 1 or claim 2 or claim 3 or claim 4 wherein the conductive filament extends proximally within the lumen of the lead body.

6. A lead according to claim 5 wherein the conductive filament extends proximally within the lumen of the lead body to the coupling means.

7. A lead according to claim 1 or claim 2 or claim 3 or claim 4 wherein the lead body comprises a slidable insulative sheath having a longitudinal lumen through which the conductive filament passes and which is movable longitudinally relative to

the conductive filament whereby the length of the conductive filament exterior to the lead may be adjusted by longitudinal movement of the slidable sheath.

8. A lead according to claim 7 wherein the slidable sheath is movable to adjust the length of the conductive filament exterior to the lead body from about two to about five inches (about five to about 13 cm.).

9. An implantable electrical lead, comprising:

an elongated insulative lead body having a proximal end and a distal end and a longitudinally extending first internal lumen and having a first aperture opening the first lumen to an exterior surface of the lead body, proximal to distal end of the lead body;

a first, coiled conductor comprising a continuous coil having first and second portions, the first portion having a first, smaller diameter and extending with the second lumen proximally from the first lateral aperture, the second portion having a second, larger diameter and extending distally from the lateral aperture, exterior to the lead body; and

means for coupling the coiled conductor to an implanted cardioverter or defibrillator.

10. A lead according to claim 9 wherein the lead body has a second lateral aperture opening the first lumen to the exterior surface of the lead body at a point distal to the first aperture and wherein the first conductor has a third portion extending distally from the second portion and extending distally from the second aperture, within the first lumen.

11. A lead according to claim 9 or claim 10 wherein the second, larger diameter is no greater than about four French.

12. A lead according to claim 9 or claim 10 or claim 11 wherein the first conductor is a multi-filar coil.

13. A lead according to claim 9 or claim 10 or claim 11 or claim 12, wherein said lead body comprises a second lumen and wherein said lead further comprises a pacing electrode mounted to a distal portion of the lead body, a second conductor coupled to the pacing electrode, extending proximally in said second lumen.

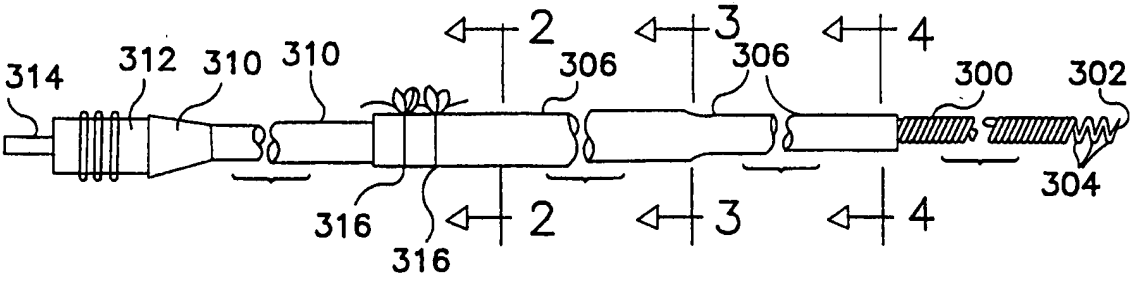


FIG. 1

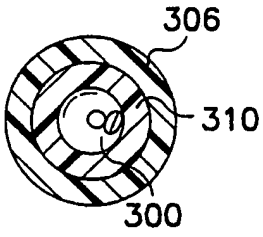


FIG. 2

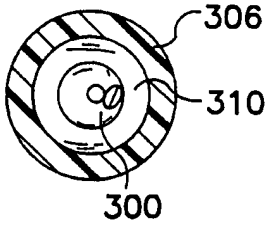


FIG. 3

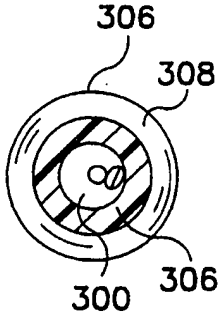


FIG. 4

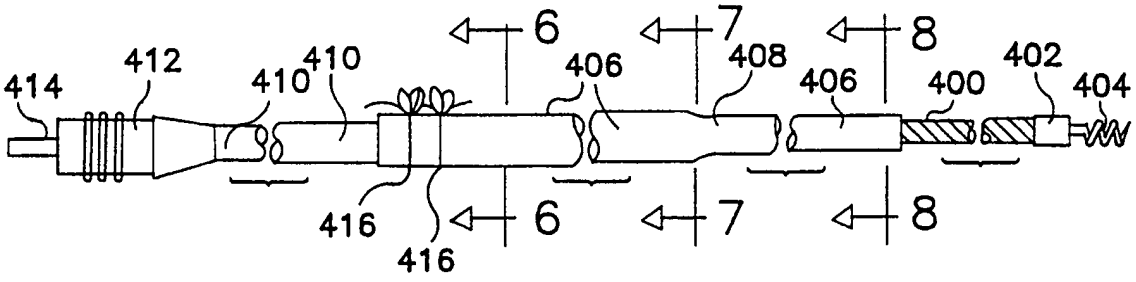


FIG. 5

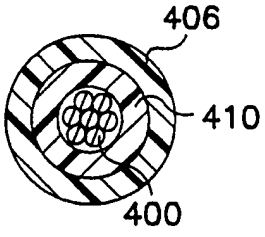


FIG. 6

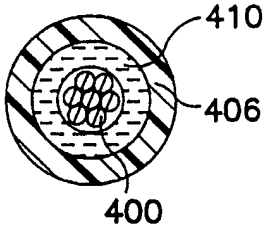


FIG. 7

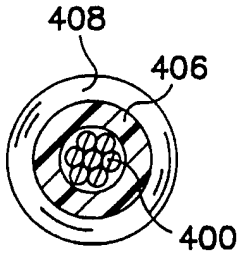


FIG. 8

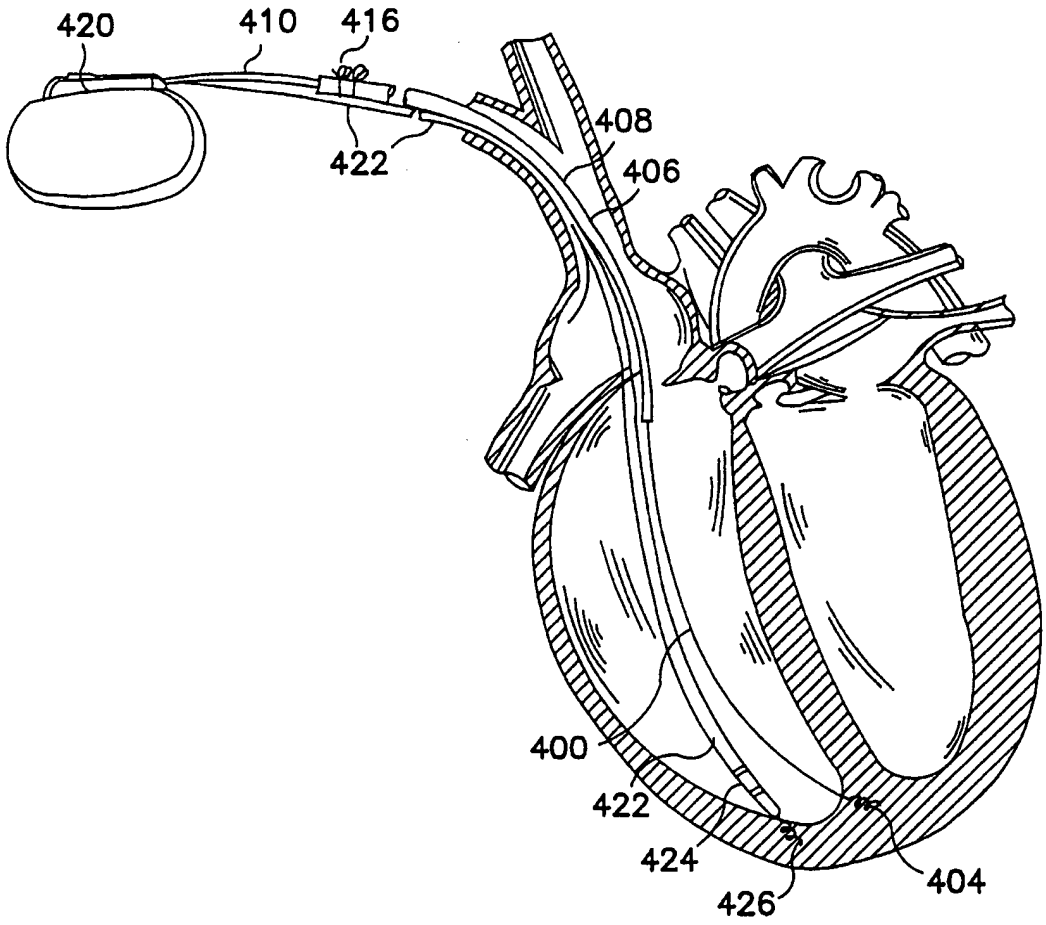
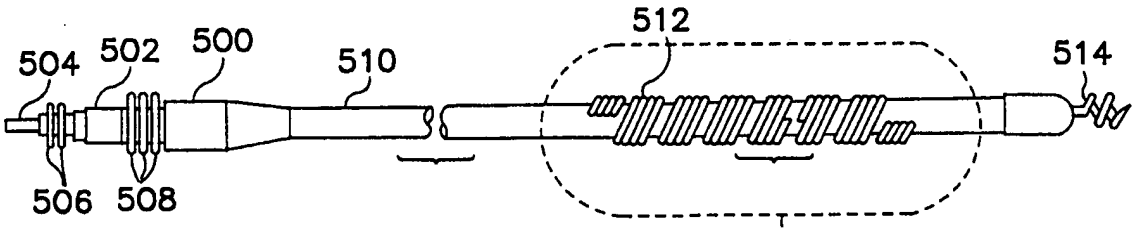


FIG. 9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512
514
506
508
11

FIG. 10

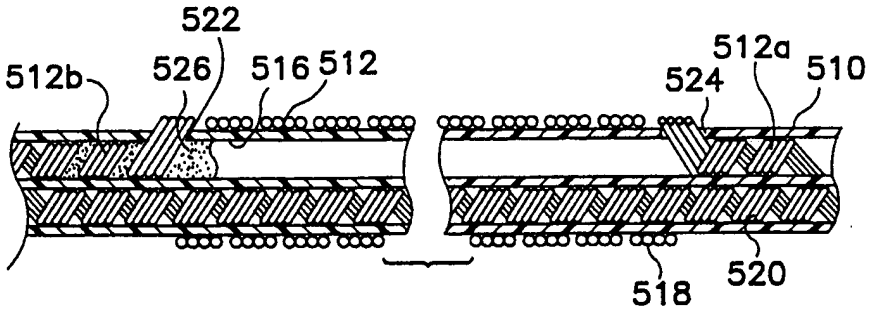
522
512b
526
516
512
512a
524
510
518
520

FIG. 11

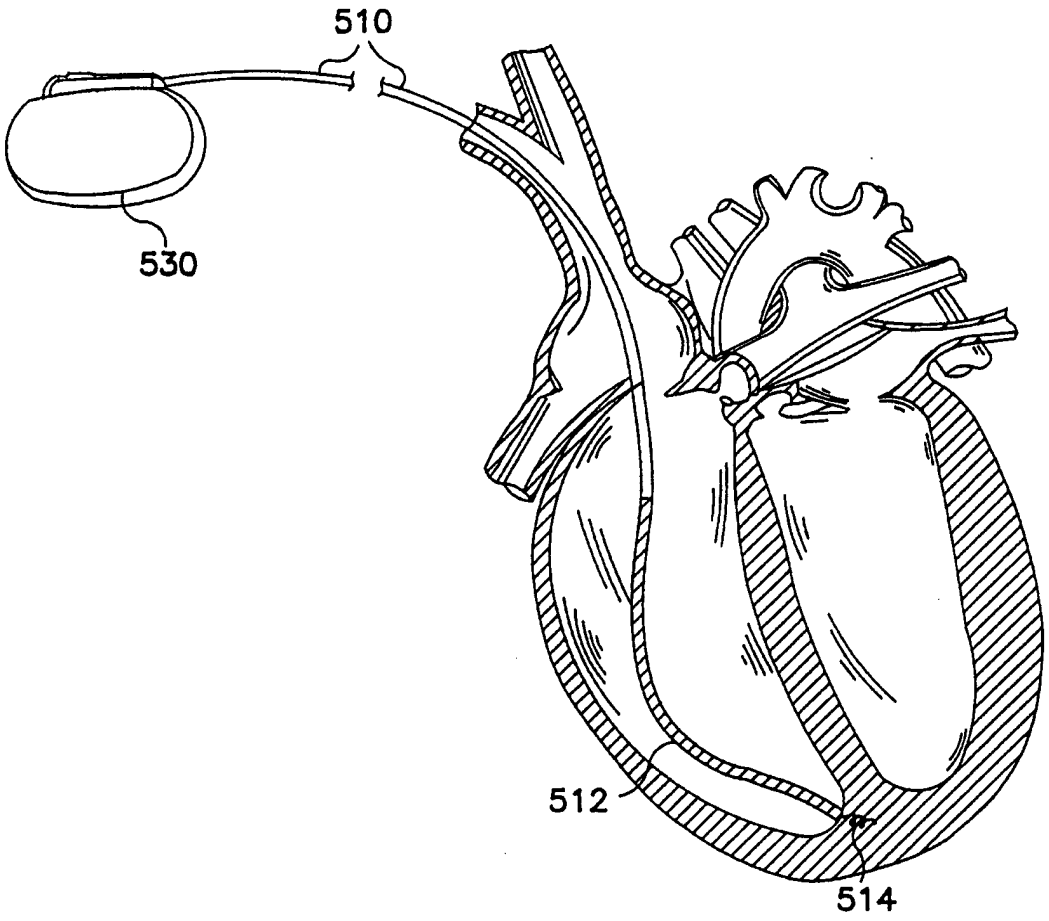

FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/05110

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 922 927 A (FINE MICHAEL J ET AL) 8 May 1990 see column 5, line 65 - column 8, line 20; figures ---	1-6,9-13
Y	US 5 534 022 A (HOFFMANN DREW A ET AL) 9 July 1996 see column 6, line 63-66; figures 1-6 ---	1-6
Y	WO 96 06655 A (ANGEION CORP) 7 March 1996 see page 9, line 18 - page 13, line 22; figures 5-10	9-13
A		1-6

A	US 5 411 544 A (MAR CRAIG E ET AL) 2 May 1995 see the whole document ---	1,5,6,9, 10,12,13
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 June 1998	01/07/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Allen, E

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INTERNATIONAL SEARCH REPORT

Inter. .onal Application No
PCT/US 98/05110

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 342 414 A (MEHRA RAHUL) 30 August 1994 see column 2, line 32 - column 4, line 14; figures	1,4,9, 12,13
A	EP 0 071 495 A (CARDIOFRANCE CO) 9 February 1983 see page 3, line 2 - page 7, line 35; figures 1-7	7,8
A	US 3 949 757 A (SABEL GEORGE H) 13 April 1976 see column 3, line 30 - column 5, line 8; figures	5-8

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/05110

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter .onal Application No
PCT/US 98/05110

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US 3949757 A	13-04-1976	NONE	